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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,743	01/03/2004	Jordan A. Altabet		1847

7590 12/09/2004
Jordan A. Altabet
7770 Regents Rd. Unit # 113-517
San Diego, CA 92122

EXAMINER

DAVIS, BRIAN J

ART UNIT PAPER NUMBER

1621

DATE MAILED: 12/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/750,743	Applicant(s) ALTABET, JORDAN A.	
	Examiner Brian J. Davis	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

The use of the various trademarks has been noted in this application. The examiner notes for the record that they should be capitalized wherever they appear and always be accompanied by the generic terminology. Applicant's assistance is respectfully requested in assuring that this has been done consistently throughout the text.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. "Group comprising" is an improper Markush group. *Ex parte Dotter*, 12 USPQ 382 (POBA 1931). See also MPEP § 2111.03.

Claims 16-18 are also rejected under 35 USC 112, second paragraph, as claims which depend from indefinite claims are also indefinite. *Ex parte Cordova*, 10 USPQ 2d 1949, 1952 (PTO Bd. App. 1989).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US PGPub 2002/0010216 A1.

First, the examiner notes that a preamble setting forth a new use does not render a known or obvious composition patentable. *In re Tuominen*, 213 USPQ 89 (CCPA 1982); *In re Pearson*, 494, F2d 1399, 181 USPQ 641 (CCPA 1964); *In re Zierden*, 162 USPQ 102 (CCPA 1969). Applicant's description of the instant composition as one meant to treat sexual dysfunction thus carries no patentable weight.

The cited reference teaches a pharmaceutical composition comprising tomoxetine (atomoxetine) as one component of a two-component composition containing a norepinephrine reuptake inhibitor (e.g. tomoxetine) and an antimuscarinic agent (page 2, paragraphs 0028-0029) in a dosage of 1-200 mg/day/patient (page 3, table below paragraph 0034) where the dosage may be incorporated in a time-release preparation (page 4, end of paragraph 0041). A norepinephrine reuptake inhibitor and an antimuscarinic agent, per force, have different "mechanisms of action."

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Claims 15-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 6,184,222 B1. As above, a preamble setting forth a new use does not render a known or obvious composition patentable. The cited reference teaches a pharmaceutical composition of a norepinephrine reuptake inhibitor, tomoxetine (column 4 line 26), in a dosage of 5-100 mg/day (column 5 line 10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,184,222 B1, cited by applicant in the specification, as applied to claim 1-18 above, and further in view of US PGPub 2002/0010216 A1.

Applicant's independent claim teaches a method for treating sexual dysfunction using atomoxetine. The dependent claims further refine the method.

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US 6,184,222 teaches a pharmaceutical composition of tomoxetine (atomoxetine) or its HCL salt (column 2 line 10; column 4 line 26 and 46) for the treatment of a behavioral disorder in children (i.e. male and female humans) (column 1 line 16) in a dosage of about 5-100 mg/day (column 5 line 10) administered by any number or routes including orally (column 5 line 28 and line 35).

US PGPub 2002/0010216 teaches a pharmaceutical composition comprising tomoxetine as one component of a two-component composition containing a norepinephrine reuptake inhibitor (e.g. tomoxetine) and an antimuscarinic agent (page 2, paragraphs 0028-0029) in a dosage of 1-200 mg/day/patient (page 3, table below paragraph 0034) where the dosage may be incorporated in a time-release preparation (page 4, end of paragraph 0041). A norepinephrine reuptake inhibitor and an antimuscarinic agent, per force, have different "mechanisms of action."

The above references may be combined because one of ordinary skill in the art at the time of the invention would have immediately conceived a time-release and/or combination formulation for a tomoxetine composition working from US 6,184,222 then given US PGPub 2002/0010216. This is so because time-release and/or combination drug formulations have been common in the pharmaceutical arts for some time and one of ordinary skill would have anticipated that tomoxetine would be also suitable.

Applicant distinguishes over the prior art only in that a method using a known composition is claimed, said method being other than that of the cited prior art.

The examiner notes that when a claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure,

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then the claim is anticipated. *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978) (MPEP 2112.02 paragraph II). This is so because a compound and its properties are inseparable. *In re Papesch*, 315, F.2d 381, 137 USPQ 43 (CCPA 1963). Thus applicant's claims to a method for treating sexual dysfunction, using a pharmaceutical composition comprising atomoxetine, are anticipated by the prior art's disclosure of a method for treating a conduct disorder, using a pharmaceutical composition containing tomoxetine (atomoxetine).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on 8:30-5:00.

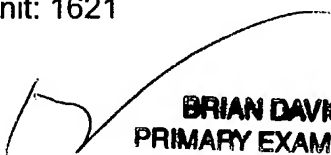
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRIAN DAVIS
PRIMARY EXAMINER

Brian J. Davis
December 7, 2004